

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
CIVIL NO. 20-1497 (DSD/DTS)

Pharmaceutical Research and
Manufacturers of America,

Plaintiff,

v.

Ronda Chakolis, James Bialke,
Amy Paradis, Rabih Nahas,
Michael Haag, Ben Maisenbach,
John M. Zwier, Barbara Droher Kline,
and Kendra Metz, in their official
capacities as members of the
Minnesota Board of Pharmacy,

Defendants.

This matter is before the court upon the motion to dismiss by defendants. Based on a review of the file, record, and proceedings herein, and for the following reasons, the motion is denied.

BACKGROUND

This longstanding dispute arises out of the 6Alec Smith Insulin Affordability Act (Act). Am. Compl. ¶ 1. Plaintiff Pharmaceutical Research and Manufacturers of America (PhRMA) is a nonprofit corporation that represents pharmaceutical companies and serves as the pharmaceutical industry's "principal public policy advocate." Id. ¶¶ 13, 15. Its member companies include Eli Lilly

and Company, Novo Nordisk Inc., and Sanofi, which collectively manufacture most of the insulin sold in Minnesota and the United States. Id. ¶ 16. Defendants are members of the Board of Pharmacy, named only in their official capacities, who enforce the Act. Id. ¶ 18. The Act requires manufacturers to provide insulin for free to Minnesota residents who meet certain criteria. Id. ¶¶ 59-67; see Minn. Stat. § 151.74.

PhRMA claims it will incur significant expenses by being forced to give away free insulin as set forth in the Act. Id. ¶ 69. PhRMA also claims that it will be unlawfully subject to penalties if it does not comply with the Act. Id. ¶ 76.

On June 30, 2020, PhRMA filed this suit alleging that the Act violates the Takings Clause of the Fifth Amendment. Compl. ¶¶ 80-85. PhRMA also asserted that one of the Act's exemptions violates the Commerce Clause, but it later withdrew that claim as moot. See ECF No.72, at 3 n.1.

Early in the case, defendants moved to dismiss the complaint for lack of subject matter jurisdiction and for failure to state a claim. The court granted the motion after concluding that PhRMA lacked standing. ECF No. 81. PhRMA appealed and the Eighth Circuit Court of Appeals reversed and remanded. The Eighth Circuit specifically held that PhRMA has standing and may seek equitable

relief on behalf of its members. Pharm. Rsch. & Mfrs. Of Am. v. Williams, 64 F.4th 932, 945-48 (8th Cir. 2023). The Eighth Circuit also concluded that PhRMA alleges a per se, physical taking rather than a regulatory taking, which means that an “ad hoc factual inquiry” as to the impact of the taking on each of PhRMA’s members is unnecessary. Id. at 947-48. Given that ruling, the issue before the court was whether the Act constitutes a per se taking of private property for public use without just compensation in violation of the Fifth Amendment.

Thereafter, in May 2024, the Minnesota legislature amended the law in two relevant ways. First, the Act now allows PhRMA’s members to seek compensation for the insulin they supply under the Act. Am. Compl. ¶ 10; Minn. Stat. § 151.74, subdvs. 3(h) and 6(h). Second, the legislature now requires insulin manufacturers to pay a \$100,000 annual registration fee, beginning on November 1, 2024. Am. Compl. ¶¶ 11, 82; Minn. Stat. § 151.741, subdvs. 1(c) and 2.¹ The registration fee must be paid in to the insulin safety net program to cover the Board of Pharmacy’s costs incurred in “assessing the collecting the registration fee ... and in

¹ Manufacturers may request an exemption from the registration fee, but PhRMA’s members would not qualify. See Minn. Stat. § 151.741, subdiv. 2(b); Am. Compl. ¶ 85.

administering" the program.² Minn. Stat. § 151.741, subdiv. 4.

These changes prompted PhRMA to file an amended complaint, alleging that the registration fee serves as an "offset" to any payments PhRMA members may receive under the amended act, and thus constitutes a continuing violation of the Takings Clause. See Am. Compl. So, although the legal claim remains the same, the issue is now focused on whether the registration fee constitutes a taking without just compensation. Defendants now move to dismiss the amended complaint.

DISCUSSION

I. Standard of Review

To survive a motion to dismiss for failure to state a claim, "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." Braden v. Wal-Mart Stores, Inc., 588 F.3d 585, 594 (8th Cir. 2009) (quoting Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)). "A claim has facial plausibility when the plaintiff [has pleaded] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal,

² The new registration fee is "in addition to the annual licensing fees manufacturers must pay to obtain a license to sell prescription medicines in Minnesota." Am. Compl. ¶ 82.

556 U.S. at 678 (citing Bell Atl. Corp. v. Twombly, 550 U.S. 544, 556 (2007)). Although a complaint need not contain detailed factual allegations, it must raise a right to relief above the speculative level. Twombly, 550 U.S. at 555. “[L]abels and conclusions or a formulaic recitation of the elements of a cause of action” are not sufficient to state a claim. Iqbal, 556 U.S. at 678 (citation and internal quotation marks omitted).

II. Registration Fee

Although the parties have raised numerous issues in their briefing and supplemental submissions, the dispositive issue before the court is whether PhRMA has plausibly alleged that the registration fee serves as an offset to the compensation the manufacturers are entitled to receive under the Act, and thus constitutes a taking under the Constitution. The court finds that PhRMA’s amended complaint has stated such a claim.

Defendants argue that the registration fee cannot be considered in the context of the Act, because it derives from a separate statute. Although technically true, the provisions at issue in both statutes were enacted at the same time and are plainly meant to work together. Indeed, the registration fee statute, Minn. Stat. § 151.741, expressly references the Act, Minn. Stat. § 151.74, and its relevant amendments:

- The registration fee, including any late fees, must be deposited in the insulin safety net program account established under § 151.74. Id. § 151.741, subdiv. 3(b).
- The insulin safety net program account is “appropriated” to the Board of Pharmacy in “assessing and collecting the registration fee” and in “administering the insulin safety net program under section 151.74.” Id. § 151.741, subdiv. 4(2).

Given this, the court finds that PhRMA has plausibly alleged that the amendments together fail to provide its members with just compensation. Specifically, PhRMA persuasively alleges that the registration fee is designed to – and does – offset the compensation its members are entitled to under the Act.

Defendants argue that if the registration fee is considered in this context, the registration fee is severable under its terms and therefore may be deemed unconstitutional without affecting the Act’s other provisions. Whether that is the case here is a question for another day.

Because the court concludes that the registration fee should be considered in the context of PhRMA’s claim, it must also conclude that PhRMA has standing to challenge the Act’s recent amendments. Indeed, PhRMA’s members are the targets of the

amendments, and they have adequately alleged concrete harm flowing therefrom. See St. Paul Area Chamber of Com. v. Gaertner, 439 F.3d 481, 485 (8th Cir. 2006) (citation omitted) ("When a statute is challenged by a party who is a target or object of the statute's prohibitions, "there is ordinarily little question that the [statute] has caused him injury.").

The court will not consider at this time whether the settlement in separate case between the State of Minnesota and one of PhRMA's members has any bearing on the merits of this case. See ECF Nos. 164, 166.

CONCLUSION

Accordingly, based on above, **IT IS HEREBY ORDERED** that the motion to dismiss [ECF No. 151] is denied.

Dated: June 3, 2025

s/David S. Doty
David S. Doty, Judge
United States District Court